ADVERSE EVENT MANAGEMENT POLICY & PROCEDURES

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Data Protection Statement

NHS Highland is committed to ensuring all current data protection legislation is complied with when processing data that is classified within the legislation as personal data or special category personal data.

Good data protection practice is embedded in the culture of NHS Highland with all staff required to complete mandatory data protection training in order to understand their data protection responsibilities. All staff are expected to follow the NHS policies, processes and guidelines which have been designed to ensure the confidentiality, integrity and availability of data is assured whenever personal data is handled or processed.

The NHS Highland fair processing notice contains full detail of how and why we process personal data and can be found by clicking on the following link to the 'Your Rights' section of the NHS Highland internet site.
http://www.nhshighland.scot.nhs.uk/Pages/YourRights.aspx

CONTENTS (please note hyperlinks to take you to relevant area/document)

Further resources are available on webpage and through the Clinical Governance Support Team

1. NATIONAL CONTEXT

Health and adult social care services in Scotland aim to provide high quality care that is safe, effective and person-centred. This is a complex system and adverse events can occur that do or could have a major effect on the people involved. Each of these events should be regarded as an opportunity to learn and to improve in order to increase the safety of our healthcare systems for everyone. Supporting cultural change is at the heart of the national framework with an aim of achieving a positive safety culture that is open, just and informed, in which reporting and learning from error is the norm. A revised framework was published in July 2018 to reflect the requirements of Organisational Duty of Candour. The fourth edition of the framework was issued in December 2019. This edition included the direction and requirements for centralised reporting of Category 1 - Significant Adverse Event Reviews (SAERs).

In line with all other Scottish Boards, NHS Highland has adopted the national framework and this policy and associated procedures have been updated to reflect the changing national frameworks.

2. OVERARCHING PRINCIPLES

The principles of the national approach to learning from adverse events support and build on the values of care and compassion; dignity and respect; openness; honesty and responsibility; quality and teamwork.

- Emphasis on learning and promoting best practice across NHS Scotland.
- System approach.
- Openness about failures.
- Just culture.
- Positive safety culture.
- Personal, professional and organisational accountability.

In addition to the above, the fourth edition of the National Framework points to the key findings of the Health Foundation Framework:

- Adverse events are a key source of intelligence about how safe care has been in the past and so have a clear place in understanding and improving safety.
- As well as learning from when things do go wrong, there needs to be a clear focus on anticipating future risks and preventing safety problems occurring in the first place.
- Learning from when things go well should also be considered.
- To get the most benefit, adverse events should be considered alongside rather than separately from other sources of data / intelligence. To illustrate, this could include information on / from: feedback; safety huddles; staffing levels; reliability of key clinical processes; team / organisation scorecards; local quality improvement work, and: mortality and morbidity reviews.
- It is important to have mechanisms in place to ensure that the learning from these different sources is integrated and acted upon.

The fourth edition of the National Framework outlined the requirement for all Boards to inform Healthcare Improvement Scotland (HIS) of any Significant Adverse Event Review commissioned for

a category 1 event from January 2020. There was also a requirement to standardise terminology across NHS Scotland.

3. INTRODUCTION

NHS Highland is committed to systematically reviewing and improving its health and adult social care processes and working practices to prevent or reduce the risk of harm. It is also committed to complying with statutory responsibilities to ensure, as far as is reasonably practicable, the health, safety and welfare of all its employees and other persons on its premises or using its services.

Adverse event reporting is one of the key methods for alerting an organisation to issues that, if left unattended, may pose a serious risk to either the patients or service users in its care, the staff it employs or to others for which it has a responsibility e.g. visitors, contractors, volunteers etc. Without an effective system the organisation may be blind to some of this risk exposure, and cannot make the necessary improvements to support safety.

It is the responsibility of everyone working for NHS Highland to report all occasions where something has happened, that has or could have caused harm to a patient, member of the public, staff member or contractor, or affected the day to day running of the organisation.

However it is recognised that reporting on occasions where things have gone wrong can be challenging, especially where there are implications for individual staff or healthcare teams. NHS Highland encourages all staff to have the confidence to report adverse events and near misses.

When an adverse event occurs, it is rarely due to an individual behaving in an unsafe or reckless way. In the vast majority of cases the causes of adverse events or near misses go beyond the actions of the individuals immediately involved, and can relate to failings in the organisation's systems and processes. People make mistakes, therefore our processes should not rely on individuals being infallible. Resorting to blaming individuals is often unfair and can be detrimental to patient safety.

We strive to embed a positive safety culture, and create an environment that is open, just and informed, in which reporting and learning from errors is the norm as per the elements of a safety culture detailed below:

Open culture
Staff feel comfortable discussing adverse events and raising safety issues with both colleagues and senior managers.

Just culture
Staff, patients, service users, carers are treated fairly, with empathy and consideration when they have been involved in an adverse event or have raised a safety issue. Duty of candour procedures are followed, and organisations are open about adverse events, apologising to the affected person.

Reporting culture
Staff have confidence in the local adverse event reporting system and use it to notify managers of adverse events that are occurring, including near misses. Barriers to adverse event reporting have been identified and removed:

- Staff are not blamed and punished when they report adverse events
- Staff receive constructive timely communication and feedback after submitting an adverse event report
- The reporting process is easy, and
- Staff will be directly involved in reviews.

Learning culture
The organisation:

- Is committed to learning safety lessons and communicating this with colleagues
- Remembers them over time, and
- Shares key learning points more widely

Informed culture
The organisation has learned from past experience and identifies and mitigates against future adverse events because it:

- Learns from events that have already happened (e.g., adverse event reviews)
- Shares key learning points
- Undertakes trend analysis and develops appropriate action plans, and
- Uses learning from adverse events to promote a positive safety culture

In health and adult social care there are a number of factors at work at any one time that can affect the likelihood of adverse events occurring. It is with this in mind that NHS Highland is committed to advocating a "Just Culture": a culture where errors or service failures can be reported and discussed, lessons learned and necessary changes put in place is essential.

There will, however, be instances where the investigation of an adverse event begins to suggest a concern about an individual's behaviour. If there is evidence of gross negligence, recklessness or criminal behaviour this will be dealt with via the Board's relevant Human Resources (HR) procedures.

The reporting and management of adverse events and near misses is an essential part of the systems and processes that support clinical governance and risk management, health and safety management and staff governance within NHS Highland. Information and data used for this purpose is captured on the DATIX Risk Management System.

4. AIMS

This policy and supporting procedures aim to ensure that all adverse events are reported, acted upon and analysed at an appropriate level and that knowledge gained is disseminated to improve quality, patient safety and performance of the organisation. This will encourage and strengthen a learning culture in which the quality of care for patients and working lives for staff will continuously improve.

Adverse event management is one part of an effective risk management strategy. Avoidance, prevention and reduction of risks should be the primary defence to prevent adverse events occurring. NHS Highland will integrate the management of adverse events with the risk management strategy and other governance processes including complaints, claims and organisational duty of candour requirements.

5. SCOPE OF THE POLICY

This Policy applies to all staff employed by NHS Highland and encompasses any adverse event affecting patients, clients, staff, volunteers, contractors or visitors (including carers, relatives and advocates).

6. DEFINITIONS

An **adverse event (or incident)** is defined as **an event that could have caused, or did result in, harm to people or groups of people.**

Harm is defined as **an outcome with a negative effect.** Harm to a person or groups of people (service users, patients, staff, carers, family, visitors) may result from worsening of a medical condition, the inherent risk of an investigation or treatment, system failure, provider performance issues, service disruption, financial loss or adverse publicity.

All harm is not avoidable, for example the worsening of a medical condition or the inherent risk of treatment. However, it is often not possible to determine if the harm caused was avoidable until a review is carried out.

A near miss is defined as an error or omission occurred which could have caused harm to a patient, member of staff or visitor or others or where a last minute intervention prevented a serious incident from occurring. Reports of near misses are helpful from a risk management perspective as they may help guide changes in procedure to avoid recurrence.

If the adverse event was a near miss the potential outcome should be considered when deciding upon the level of investigation.

ADVERSE EVENT CATEGORISATION

The national adverse event framework uses the following categorisation of adverse events. This is based on the ***consequence*** rather than the overall grade of the adverse event.

Category 1 - Events that may have contributed to or resulted in permanent harm, for example unexpected death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity (likely to be graded as major or extreme impact). See Appendix A for more information on adverse events which could be considered as Category 1.

Category 2 - Events that may have contributed to or resulted in temporary harm, for example initial or prolonged treatment, intervention or monitoring required, temporary loss of service, significant financial loss, adverse local publicity (likely to be graded as moderate impact).

Category 3 - Events that had the potential to cause harm but no harm occurred, for example near miss events (by either chance or intervention) or low impact events where no harm resulted (likely to be graded as minor or negligible).

See Procedure 2 for more guidance on category grading and level of review. The following table provides a summary on the approach to take based on categorisation.

Category	Level of Review	Review Team	Reporting Findings and Learning	Guidance Timescale
Category 1	Level 1 review Significant Adverse Event Review (SAER)	Director / AMD / Lead Nurse / relevant Head of Service to appoint full review team; provide terms of reference and commission review. The review team should be appropriately skilled and be able to provide an objective view	Report to be submitted to Operational Unit (OU) Quality and Patient Safety Sub-Group for ratification and approval of actions. OU Quality and Patient Safety Group to oversee implementation of actions	Commission review within 10 working days of the adverse event report Commence and submit report for approval within 90 working days of the commissioning date. Final approval and development of improvement plan ASAP and no later than 30 working days from report submission. Also note timescales for communicating with patient / family within Duty of Candour.
Category 2	Level 2 review Local Management Review Note: If the adverse event meets duty of candour review may be commissioned by AMD / Lead Nurse as per Cat 1 / Level 1 review	Manager in charge of the department or area in consultation with staff. If thought to meet duty of candour, AMD / Lead Nurse commission person(s) to undertake review	Improvement / action plan to be developed and reported through Operational Unit management structures If review commissioned due to Duty of Candour, to be reported, ratified and monitored as Category 1 above	Commence and close review (report submitted for approval) within 30 working days of the adverse event being reported on incident management system. Final approval and development of action plan ASAP and no later than 30 working days from report submission. Also note timescales for communicating with patient / family within Duty of Candour.
Category 3	Level 3 Local investigation	Managers / staff locally according to requirements	N/A unless trends require a review then a plan should be developed	Adverse event approved and closed within 10 working days of adverse event being reported on incident management system.

7. ROLES AND RESPONSIBILITIES

All staff have a responsibility to:

- Take care of their own safety and that of others including patients, service users, colleagues, volunteers, contractors or visitors;
- Eliminate unlawful discrimination and unlawful harassment, promote equality of opportunity and promote good relations between different population groups;
- Report any adverse event or near miss to their manager or other responsible person;
- Complete a DIF1 Form and submit this to the appropriate manager as soon as is practical to do so after the adverse event has been dealt with, and ideally within 24 hours, participate in investigations and remedial actions as appropriate;

Reviewers have a responsibility to:

- Ensure that, as a first priority, any person affected by an adverse event receives appropriate first aid or medical treatment; ensure that action is taken to prevent further danger to others. Equipment involved in the incident must be made safe, removed from use and retained for inspection. In exceptional circumstances, the surrounding area of the event should be isolated, pending any necessary analysis;
- Ensure that reporting procedures are complied with in the event of any adverse event affecting any person or premises for which they are responsible, including the completion of an initial action plan; including ensuring staff report the adverse event on the DIF1 form ideally within 24 hours of the adverse event occurring.
- Arrange a debrief for staff involved in the adverse event at the outset and at later points as required.
- Ensure that staff involved in an adverse event are given appropriate support including access to Occupational Health Service or other relevant services if required;
- Identify and escalate RIDDOR Reportable Adverse Events to the Health and Safety Team as soon as possible after the Adverse Event for advice and guidance and to ensure timely reporting to HSE.
- Undertake reviews of adverse events and near misses, in liaison with other managers where necessary; Grading and reporting details of investigation regarding the adverse event on the DIF2 within agreed timescales;
- Ensure any significant adverse events and / or potential Organisational Duty of Candour events are reported to the relevant Deputy and Associate Medical Director and Lead Nurse.
- Involve and consult accredited staff side H&S representatives, making information and knowledge of adverse events available;
- Monitor trends within their area of responsibility; use pre-set reports to monitor trends in own

area and share this information with staff;

- Contribute to dissemination of lessons learned and implement any actions identified as their responsibility, or the responsibility of their team.

Deputy Associate Medical Directors / Lead Nurses / Professional Leads have a responsibility, via the Quality and Patient Safety Groups / HSCP Clinical Governance Committee to:

- Ensure systems are in place to review all reported adverse events and near misses within their areas on a regular basis and agree any necessary actions or improvements required;
- Ensure systems are in place to provide feedback on local adverse events reviews and near misses to Quality and Patient Safety Groups / HSCP Clinical Governance Committees as necessary;
- Initiate a review of significant adverse events, near misses, potential Organisational Duty of Candour events in liaison with specialist advisors and staff side H&S representatives where necessary;
- Ensure systems are in place to assess all near misses and adverse events including Organisational Duty of Candour incidents weekly and where appropriate implement action plans to address root causes identified to ensure that learning is disseminated;
- Where relevant ensure that adverse events are finally approved within the DATIX system and that all investigations where actions are outstanding are followed up within the agreed timescales.
- Ensure consideration is given to findings and recommendations from significant adverse events occurring elsewhere in Highland which have wider relevance

Specialist Advisors / Managers (e.g. Health & Safety Managers / Advisors, Moving and Handling Manager, Management of Violence & Aggression Manager / Advisors, Clinical Governance Managers / QPS Facilitators etc.) have a responsibility to:

- If the incident arose out of or in connection with work activities and/or is reported under RIDDOR to the HSE, Health and Safety advice and support should be sought. This may include clinically orientated tasks and functions e.g. bed rail management, choking patients, wandering patients/clients etc.
- Provide advice, guidance and support to managers and other employees around adverse events, including Organisational Duty of Candour.
- Assist in adverse event analysis as required. Provide expert advice on root cause analysis of incidents as necessary and appropriate assistance to ensure incident reports are prepared within the agreed timescale;
- Make recommendations to reduce risk based on incident analysis;
- Ensure systems are in place to review findings and recommendations from significant adverse events occurring elsewhere in Highland which have wider relevance

The Clinical Governance Committee, Staff Governance Committee and Health & Safety Committee have a responsibility to:

- Ensure that the organisation develops and sustains a Safety Culture and a culture of reporting and learning from adverse events and near misses;
- Receive regular reports on trends and outcomes of adverse events and near misses from the Clinical Governance Support Team and Health & Safety Team;
- Receive reports on specific significant adverse events;
- Monitor to ensure that appropriate action and learning has taken place following the identification and reporting of adverse events and near misses to contribute to learning and improvement

8. ADVERSE EVENT MANAGEMENT

To support the management of adverse events, detailed procedures have been developed which cover:

1. Initial management of an Adverse Event; Reporting; Grading and Timescales
2. Carrying out an Adverse Event Review Investigation: General Guidance
3. Carrying out a Category 1, Level 1 review/ Significant Adverse Event Review
4. Learning From Adverse Events
5. Being Open and Involving Patients, Service Users, Carers when an Adverse Event has Occurred
6. Joint Working and Multi-Agency Issues
7. Supporting Staff Following an Adverse Event

9. COUNSELLING & SUPPORT FOR STAFF

As noted above under 'Responsibilities', Managers are responsible for ensuring that staff are given the opportunity to be de-briefed following an adverse event with serious or potentially serious consequences. Managers must ensure that staff are informed of how to access Occupational Health Services, Chaplaincy Service and Psychology Services if appropriate and other counselling / therapy services.

Managers should ensure that staff are encouraged to seek support from accredited staff side representatives where appropriate.

For further information please use link to Guidance on Supporting Staff.
Guidance of Supporting Staff

10. TRAINING AND EDUCATION

In order to facilitate an open and transparent adverse event reporting culture and to support the implementation of this policy throughout NHS Highland, the Clinical Governance Support Team and the Health and Safety Team will provide training to staff across the organisation.

All new staff will be shown as part of induction in "how to log an adverse event" by using the resources available.

The Clinical Governance Support Team and Health and Safety Team will provide training on any aspect of adverse event management including basic investigation and root cause analysis as required

Resources and Tools are available from the Clinical Governance Support Team.

11. INFORMING THE NHS BOARD

Any Level 1 review / Significant Adverse Event Review or adverse event that could impact on the reputation of the organisation should be alerted directly to relevant members of the executive / senior leadership team for consideration of alerting the NHS Highland Board.

Where a significant adverse event occurs within an Operational Unit, the Board Medical Director, Board Nurse Director and Chief Executive should be informed once the initial facts have been gathered and a decision to carry out a significant event review has been taken. They will be responsible for informing other Board members.

When a Board-wide adverse event occurs (e.g. relating to Public Health concerns) or where there is likely to be widespread public concern or media interest, then all the Non-Executive Directors should be informed once the initial facts have been gathered and a decision to carry out a significant adverse event review has been taken.

The relevant Non-Executive Directors will be updated as appropriate during the course of the significant adverse event review.

12. DEALING WITH THE MEDIA

Managers should prepare for media interest in any serious adverse event. There are significant reputational risks where incorrect treatment is given or where groups of people are put at risk as a result of failures in, for example: infection, prevention and control, diagnostic reporting processes or where there has been an outbreak of food poisoning.

At all times patients, service users and their relatives and staff must be notified about the findings from an adverse event before informing the media. Patient, service user and staff confidentiality must be maintained at all times and consent to share personal information must be obtained prior to sharing with the media or other bodies.

Communications with media will only be via the Chief Executive, Head of Public Relations and Engagement, Communications Managers or other senior managers identified for the purpose.

13. MONITORING AND REVIEW

This Policy will be reviewed in three years, and sooner in line with any national updates.

PROCEDURE 1 -
INITIAL MANAGEMENT OF AN ADVERSE EVENT, REPORTING, GRADING & TIMESCALES

INITIAL MANAGEMENT

On discovery of an adverse event the priority is that any person affected should receive appropriate first aid or medical treatment. The Person in Charge must ensure that this is done, and that action is taken to prevent any further injuries / damage to the affected person or to others.

If the adverse event is serious or if an emergency situation arises, appropriate staff should be contacted, Associate Medical Director, Lead Nurse, Director / Head of Community Services/ Acute Services, or on-call manager (out of hours).

In cases where a patient / service user has been involved in an adverse event, they must be informed where possible before informing relatives/carers.

Equipment involved in the adverse event must be made safe, removed from use and retained or isolated for inspection. Where possible, the surrounding area of the event should be isolated, pending any necessary investigation.

REPORTING AN ADVERSE EVENT

All adverse events, including near misses, must be reported via the DIF1 form in Datix (nugget on the intranet) within one working day. Until an initial analysis of the circumstances of the adverse event takes place an informed decision cannot be made about the implications.

The DIF1 must be completed by the person(s) involved in the adverse event with assistance from the Person in Charge if necessary and witnesses where required. The person completing the DIF1 should record only known facts, not opinions and should not assign fault or blame. The form is a legally disclosable document.

The person completing the DIF1 will select a manager to submit the adverse event to. This Reviewer is deemed the “Reviewer” (previously referred to as the handler) of the adverse event and is responsible for reviewing the information submitted on the DIF1 and completing the DIF2 and grading the adverse event (see below) the outcome of which will determine the level of investigation required.

NHS Highland recognises some staff do not have easy access to a computer. It is the responsibility of each department which envisages a problem with computer access to ensure that they nominate an administrative person who can assist staff to report adverse events via the DIF1.

TYPES OF ADVERSE EVENTS TO BE REPORTED

Staff should report anything that causes them concern. The overlying principle which should be followed is “any event arising during NHS Highland's care or service provision that could have caused or did result in, harm to people or groups of people”. This definition includes near misses. A near miss is where an error or omission occurred which could have caused harm to a patient, member of staff or visitor or others or where a last minute intervention prevented a serious adverse event from occurring. Examples of the types of adverse events which should be recorded on a DIF1 form are shown in Appendix C.

The categories enable a broad range of adverse events to be reported. Datix should not be considered the only way to communicate an adverse event. Staff should also bring the adverse events to the attention of their colleagues to discuss and resolve.

For advice on the category of the adverse event, contact the Clinical Governance Support Team

ASSESSMENT, CATEGORISATION AND GRADING

All events are subject to review. The basic process of adverse event review and analysis is essentially the same. Some events, due to complexity or potential for learning require a more formal, extensive review to comprehensively examine the chronology, care delivery problems and contributory factors.

The category of the event will support the decision-making process for the level of review required. A severe or tragic outcome is not the only determining factor. Near miss events with no adverse outcome and complex lower severity adverse events (Category 3) can also warrant high level review if there is potential for learning.

The aim is to gain an insight on underlying weaknesses of the system or areas where the system could be improved. The following decision-making prompts may help to determine the potential for learning:

- Is the outcome a known complication of the disease, treatment or process?
- Has there been any known breach or deviation in policy or procedure?
- Are there unknowns surrounding the event?
- Does the event activate duty of candour procedures?
- Is there learning to be gained/would staff do anything differently next time?
- Is the patient, service user, family or management concerned about the event?

An event being subject to a Level 1 review / significant adverse event review does not automatically indicate a causal link between care or service delivery and the outcome, or suggest the event was avoidable. It reflects the perceived need to review the event in detail to establish the facts of what happened to determine any links between the care delivery and the outcome or that there is potential for learning to inform system / service improvement

The risk grading process developed by NHS Scotland is based on the Risk Assessment Matrices sourced from AS/NZS 4360:2004 Making it Work (2004).

The reviewer to whom the adverse event is submitted, the “Reviewer”, should grade the adverse event on the DIF2 using the process described below. This process should be completed as soon as the reviewer is made aware of the adverse event.

The grading of any adverse event is determined by two factors: The severity of consequence or outcome of the adverse event; or for near misses the potential

- The probability or likelihood of the adverse event occurring / reoccurring.

Each adverse event should be assessed and scored for likelihood and severity.

Grading adverse events in this way will then establish:

- The level of investigation
- The internal reporting requirements

These are described in more detail in the following Procedures

PROCEDURE 2 - CARRYING OUT AN ADVERSE EVENT REVIEW INVESTIGATION: GENERAL GUIDANCE

The national adverse event framework uses the following categorisation of adverse events indicating the level of review. This is based on consequence rather than the overall grade of the adverse event

Adverse Event Category	Level of review	Review team	Reporting of findings and learning	Guidance timescale
Category 1 Events that may have contributed to or resulted in permanent harm, eg unexpected death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity **(likely graded major, extreme)**	**Level 1** Significant Adverse event analysis and review	Full review team: Director / AMD / Lead Nurse / relevant Head of Service to appoint full review team; provide terms of reference and commission review. The review team should be appropriately skilled and be able to provide an objective view	Report to be submitted to Operational Unit Quality and Patient Safety Sub-Group for ratification and approval of actions. Operational Unit Quality and Patient Safety Group to oversee implementation of actions AMD to share findings in exception report to CGC	Commission review within 10 working days of the adverse event being reported on datix Commence and close review (report submitted for approval) within 90 working days of the commissioning date. Final approval should take place as soon as possible and no later than 30 working days from report submission. Develop improvement plan within 10 working days from report being approved Please also note specific timescales for communicating with patient/family within Organisational Duty of Candour.
Category 2 Events that may have contributed to or resulted in temporary harm, eg initial or prolonged treatment, intervention or monitoring required, temporary loss of service, significant financial loss, adverse local publicity **(likely to be graded as r moderate impact).**	**Level 2** Local Management Review If meets requirements of organisational duty of candour review may be commissioned by AMD / Lead Nurse as per Cat 1 / Level 1	Manager in charge of the department or area in consultation with staff. If thought to meet duty of candour, AMD / Lead Nurse commission person(s) to undertake review	Improvement/action plan to be developed and reported through Operational Unit management structures If review commissioned due to Duty of Candour, to be reported, ratified and monitored as Category 1 above	Commence and close review (report submitted for approval) within 30 working days of the adverse event being reported on incident management system. Final approval should take place as soon as possible and no later than 30 working days from report submission. Develop improvement plan within 2 weeks from report being approved. Please also note specific timescales for communicating with patient/family within Organisational Duty of Candour.
Category 3 Events that had the potential to cause harm but no harm occurred, for example near miss events (by either chance or intervention) or low impact events where no harm resulted **(likely to be graded as minor or negligible).**	**Level 3** Further inquiries/questions Trends should be considered for further review	Managers / staff locally If further review required then local management review process	Not applicable unless trends require a review then a plan should be developed to address the outcome	Adverse event approved and closed within 10 working days of adverse event being reported on incident management system.

Note: the level of review should not only be mandated by the categorisation of the event as other factors also impact this decision such as the characteristics of the event, the patient or service user, the service, the outcome and the potential for learning.

Timing is important, if there is a significant delay, conditions may change and memories will become clouded. It is therefore important to assemble the relevant people as quickly as possible. For this reason timeframes are applied to any adverse event review.

It should be noted that there is a statutory duty to report certain types of adverse events within defined timescales. Refer to RIDDOR Appendix

In addition to grading, the relevant Reviewers should use their experience and judgment on what level of investigation needs to be undertaken. In some cases it may be more helpful to consider the potential consequence / outcome, especially with near misses.

Following initial reporting of an adverse event or near miss, the relevant reviewer will assess the adverse event reporting form to consider whether a more in-depth review of the event is required. It is important that the level of review is proportionate to the consequence of the adverse event. Adverse event reviews aim to establish the contributing factors of an adverse event, with a view to reducing the likelihood and / or impact of similar future events. Other parties may need to be involved, e.g. Health & Safety Manager, Clinical Governance Managers, other Specialist Advisors (i.e.: Tissue Viability Leads, Falls Co-ordinators, Pharmacists etc), especially where an outside impartial viewpoint is essential.

The level of review will depend upon the severity of the outcome and other factors. As a guide:

Category 1 Adverse Events - those graded with a consequence of MAJOR or EXTREME

Likely to have a significant outcome and require consideration for a Level 1 review / Significant Adverse Event Review (SAER). A DIF2 form will require to be completed for these adverse events and the Reviewer should escalate the adverse event to the Associate Medical Director, Lead Nurse, Director / Relevant Head of Service as per procedure 3.Adverse events graded as Major or Extreme will also be screened for Organisational Duty of Candour at the time of reporting

Category 2 Adverse Events - those graded with a consequence of MODERATE

These adverse events require some investigation as to what happened and why.

Managers will require to grade the adverse event on the DIF 2. The Reviewer should read any analysis and determine what actions are required to reduce or remove the risks, and any underlying causes, organisational, environmental, team or individual.
The Reviewer may involve more senior personnel and consult with subject experts as necessary
The outcome of the analysis together with any recommended actions should be reported to the Directorate / Locality / District Manager who have a responsibility to ensure that they monitor adverse events and ensure that actions recommended have been acted upon and are working.

Adverse events graded as Moderate will also be screened for Organisational Duty of Candour at the time of reporting
The Reviewer must ensure that the DIF2 of the Datix is fully completed and finally approved.

Summarised reports and action plans should be presented to the relevant Quality & Patient Safety / Clinical Governance & Risk Management Groups. These groups are responsible for monitoring progress with action plans and sharing learning.

Category 3 Adverse Events - those graded with a consequence of MINOR OR NEGLIGIBLE

Usually simple adverse events, dealt with by the Reviewer.

The Reviewer will review the information submitted and grade the adverse event on the DIF2 and may involve more senior personnel, consult with subject experts as required

The frequency of this type of adverse event should be given careful scrutiny and consideration given to carrying out a risk assessment.

Consideration should be given to how this adverse event might be prevented bearing in mind that inadequate control measures could result in a more serious adverse event in the future

The Reviewer must ensure that the DIF2 of the Datix is fully completed and finally approved.

Reviewers should be monitoring for trends.

Every adverse event will require an assessment to establish the cause. This will range from a minimal review where the root cause is well known and is already being addressed via other means, or the adverse event has been risk assessed and is as low as it can be, through to a serious adverse event which will give rise to a full and immediate analysis. 'Root Cause Analysis' is used to describe the process necessary to establish the true cause of a problem and the actions necessary to eliminate it. Resources are available from the Clinical Governance Support Team and on the web page

Undertaking an Investigation

The following is a list of factors which are recommended to be included in an analysis of the adverse event, dependent on the nature of the adverse event and the work area involved:

1 The precise location
2 The precise time and date
3 Who was involved in the adverse event
4 The normal occupation of the person involved if an employee
5 Exactly what happened including:
6 Exactly what the person was doing at the time
7 The conditions at the time (e.g. lighting, weather, housekeeping)
8 The causes of the adverse event
9 Which standards were not met or deviated from
10 The nature of any injuries or damage which occurred including:
11 What inflicted the injury or damage
12 Description of any equipment involved in the adverse event
13 An assessment of the grading of the adverse event including the potential severity and the chance of recurrence
14 The causes (contributory factors) of the adverse event
15 The measures to prevent a recurrence - immediate and future
16 Details of any witnesses to the adverse event

The Reviewer should speak to all parties involved, particularly those named in the DATIX.

The Reviewer should make an assessment as to whether written factual accounts / statements are required and make arrangements for these to be obtained as necessary. Further information is in the resource pack.

NEAR MISSES

The above categorisation is based on impact of harm and could support the measurement of reported events that resulted in harm versus those which did not result in harm.

It is acknowledged that we should be aiming to take a preventative rather than reactive approach and we should not wait for harm to occur before making improvements to the system. Therefore consideration of the potential for learning from the event should also determine the level of review required. This aims to ensure that responses are not overly focused on the impact or outcome of that particular event but are used to gain an insight on underlying weaknesses of the system. It is likely that some near misses provide the most learning opportunities and therefore be considered as a Category 1 adverse event.

PROCEDURE 3

CARRYING OUT A CATEGORY 1, LEVEL 1 REVIEW / SIGNIFICANT ADVERSE EVENT REVIEW

See Appendix A for the types of adverse events which should be considered as **Category 1 adverse event requiring a Level 1 review / Significant Adverse Event Review**

Declaring a Level 1 review / Significant Adverse Event Review
Where an adverse event is reported which appears to fulfil the definition of a Category 1 adverse event, a Level 1 review / SAER must be considered. The need for an SAER must be agreed by two of these individuals; the Deputy / Associate Medical Director, Lead Nurse or the Head of Community Services / Head of Acute Services. For Corporate Services this would be two Executive Directors. Organisational Duty of Candour must also be considered.

Communication of a Level 1 review / SAER review must be made to the Chief Executive, Board Medical Director and Board Nurse Director.

Once a Level 1 review /SAER review has been declared the Level 1 review /SAER review must be carried out in line with the guidance for Carrying Out a Category 1, Level 1 Review / Significant Adverse Event Review.

PROCEDURE 4 - LEARNING FROM ADVERSE EVENTS

The comprehensive system of reporting and analysing adverse events and near misses will result in the collection of considerable quantities of useful data. This information can be used to show trends, acting as an early warning system for both potential and realised problems. It can also provide timely information on possible future liabilities.

A summary of outcomes and actions taken following an adverse event review will be provided to the individual who reported the adverse event and to those who were involved in the adverse event analysis. The summary will be prepared taking full account of duties with regard to confidentiality. A feedback email from Datix will be sent to the individual reporting the adverse event at the time of reporting and at the time the Datix has been finally approved.

The reporting of adverse events and near misses will enable trends to be identified and reported throughout the organisation in order that appropriate action may be taken, learning disseminated and better quality services delivered.

The Clinical Governance Support Team provides information on adverse events via Quality and Patient Safety Dashboards and adhoc reports to:

- The Clinical Governance Committee;
- The Health & Safety Committee;
- Operational Unit Quality and Patient Safety Groups
- Area Drug & Therapeutic Committee and / or its sub-groups.
- Area Nursing and Midwifery Committee and / or sub-groups

All managers have access to their own data via the “My Reports” section. This can allow regular local monitoring of trends at ward level and managers should share this information with their staff on a regular basis.

A learning summary of completed significant adverse events is uploaded to the “When things go wrong” webpage, which is accessible on the front page of the NHS Highland intranet.

A Quality and Patient Safety Dashboard has been designed by the Clinical Governance Support Team to enable further interrogation of data and trends.

Patient Alerts and Newsletter
Improvement plans including audit and training and education, risk management

PROCEDURE 5 - BEING OPEN AND INVOLVING PATIENTS, SERVICE USERS, CARERS WHEN AN ADVERSE EVENT HAS OCCURED

Communicating effectively with patients, service users and/or their carers is a vital part of the process of dealing with errors or problems in their care and treatment. In so doing, NHS Highland can hopefully reduce the trauma suffered by people and potentially reduce complaints and litigation. If the Organisational Duty of Candour procedure has been activated in relation to an adverse event, there is a legal requirement to ensure that patients, service users and their families are communicated with effectively. This procedure is intended to be a brief overview of the key principles.

As soon as possible after an adverse event has occurred the patient, service user, carer should receive:

- An apology. Saying sorry is not an admission of liability and it is the right thing to do. People have a right to expect openness in their care. The apology should be a sincere and compassionate statement of regret for the distress that the person is experiencing due to the adverse event.
- a factual explanation of what happened;
- a clear statement of what is going to happen from then onwards;
- a plan about what can be done medically to repair or redress the harm done.

Throughout the process, consideration must be given to the following points:

- The lead person should normally be the most senior clinician responsible for the patient's care and/or a clinician with experience and expertise in the type of incident that has occurred.
- Continuity is important in building relationships.
- Meetings should be supported by others who can take notes and respond to questions
- Patients, service users, carers should be offered the opportunity to bring their own support
- Each team member should communicate clearly, sympathetically and effectively.
- Hold a pre-meeting so that the team knows the facts and understands the aims of the meeting.
- Hold meetings as soon as reasonably practicable and at a time and place convenient to the person's home and social circumstances.
- Hold meetings in a quiet room where there will be no distractions or interruptions and away from the place where the incident occurred if this is likely to be difficult for the person
- Use clear, straightforward language and avoid jargon or acronyms
- Consider the needs of patients, service users and/or carers with particular requirements, for example, language or cultural needs, those with mental health problems or learning difficulties.
- If appropriate, suggest sources of support and counselling.
- Check that the patient, service user and/or carers have understood what they have been told and offer to answer any questions.
- Provide a named contact if the person wishes to speak with staff again.
- Clarify in writing the information given, reiterating key points, recording action points and assigning responsibilities and deadlines.
- Maintain a dialogue with the patient, service user and/or their carers by addressing any new concerns, sharing any new information once available and providing information on counselling, as appropriate.

For more detailed information relating to activation of the Organisational Duty of Candour procedure and communicating with patients and families please contact the Clinical Governance Support Team. Link app

PROCEDURE 6 - JOINT WORKING AND MULTI AGENCY ISSUES

Every effort should be made to work with other NHS bodies and external agencies to investigate incidents that cross organisational boundaries. This might involve staff from each organisation working on a joint investigation, or people from different organisations working together to create an Incident Team. This will be overseen by the Chief Officer or the Director of Adult Social Care.

Child Protection (SG)

All agencies which work with children have a shared responsibility for protecting children and safeguarding their welfare. Each has a different contribution to make to this common task.

Inter-agency review of critical incidents is an important way to identify and improve all interagency practice. Such reviews allow inter-agency guidelines and agreements to be evaluated and changed if necessary, and are an important source of learning for the improvement of practice. NHS Highland is fully committed to this process.

The Highland Child Protection Committee has issued Child Protection Guidelines, which include a detailed Critical Incident Review Protocol. The Highland Child Protection Committee will always consider whether a review is necessary when:

- a child dies who was registered on the Child Protection Register;
- a child has sustained a potentially life threatening injury through abuse or neglect, sexual abuse, or sustained serious and permanent impairment of health or development through abuse or neglect and the case gives rise to concerns about the way in which local professionals and services worked together to protect the child.

The Child Protection Committee may also consider whether to undertake a Serious Case Review where there has been significant inter-agency planning and working in a case. New protocols, procedures or guidance may be required to ensure dissemination of any good or new practice undertaken.

The Child Protection Guidelines recognise that individual agencies may conduct internal management reviews of cases independently of any inter-agency review. Such reviews will inform interagency review. Within NHS Highland any such review will follow the procedures set out in the Serious Adverse Event Review.

Guidance and additional information can be obtained from the Clinical Governance Support Team.

Adult Support and Protection – Significant Case Review Guidance

Guidance on carrying out a Significant Case Review involving Adult Support and Protection is available
via link Significant Case Review local protocol Sept 2018.

Guidance and additional information can be obtained from the Adult Protection Lead Advisor. Further information can be obtained from the Clinical Governance Support Team.

PROCEDURE 7 – SUPPORTING STAFF FOLLOWING AN ADVERSE EVENT

NHS Highland recognises the importance of looking after the psychological as well as the physical needs of staff who have experienced or been exposed to an adverse event.

As individuals, people can respond differently to incidents and there is no one size fits all. Guidance has been prepared which offers advice and approaches that can be used to support staff and highlights services which are available to provide more specialist support if required.

It is important to ensure that staff are well supported during such events, in particular:

- *staff are debriefed*
- *staff are well informed*
- *proceedings happen as quickly as possible*
- *staff are well supported by their peers*

Staff may find both the initial incident and any subsequent review process difficult.

A debrief with staff should be held as soon after the adverse event as possible. A debrief is a semi-structured conversation with individual(s) who have experienced a stressful or traumatic event. The purpose of a debrief is to allow individuals to talk about their experiences. This can involve factual discussion about what happened and also refer to their thoughts and feelings at the time. Debrief should not be considered as a single, one-off event.

For more detailed guidance please follow this link – **Guidance and Supporting Staff**

At the end of an adverse event review it is good practice to debrief staff on the findings and conclusions of any review or investigation. This can be done on an individual / group basis dependent on the issues raised. It may also be useful to involve staff wider than those involved in the adverse event to allow for discussion on the next steps also.

APPENDIX A

Guidance on a Category 1 Event Requiring a Level 1 review / Significant Adverse Event Review

The following events shall all be considered as potential **significant adverse events** and assessed against the Level 1 review descriptor:

1. All adverse events reported in DATIX where initial review suggests potential deficiencies in care resulting in death or life saving intervention, or permanent / long term harm (ie: major / extreme graded consequence).

2. Any adverse event where Organisational Duty of Candour is believed to apply, particularly the following categories:

- A person died
- A person incurred permanent lessening of bodily, sensory, motor, physiologic or intellectual functions
- The structure of a person's body changed
- A person's life expectancy shortened
- A person needed health treatment in order to prevent them dying

3. "Never Events" *(NHS Improvement Never Events Policy & Framework)*

- Surgical – wrong site surgery, retained foreign object post-surgery, wrong implant / prosthesis, unexpected anaesthetic intra-operative or immediate post-operative death.
- Medication errors – mis-selection of a strong potassium solution, mis-selection of high strength midazolam during conscious sedation, administration of medication by the wrong route, overdose of methotrexate for non-cancer treatment, overdose of insulin due to abbreviations or incorrect device, other medication errors resulting in death, lifesaving intervention or permanent or long term harm.
- Mental health – suicide / attempted suicide of an inpatient on hospital premises, suicide in the community where there has been significant suicide risk identified in the last contact prior to death, suicide of an inpatient on pass or during unauthorised absence from the ward, unexpected deaths meeting the "HIS Suicide Review Criteria"
- Maternity – maternal deaths where initial review suggests potential deficiencies in care, perinatal / neonatal deaths where initial review suggests potential deficiencies in care
- General – death of a patient after an in-patient fall, missed diagnosis of cancer or life limiting condition, death from sepsis, transfusion or transplantation of ABO incompatible blood components or organs, scalding of patients, undetected oesophageal intubation, falls from poorly restricted windows, grade 3 or 4 pressure ulcers acquired in hospital with no previous skin problems, chest or neck entrapment in bed rails, unintentional connection of a patient requiring oxygen to an air flow meter, misplaced naso-gastric or oro-gastric tubes

4. Other non-patient adverse events (staff, contractors, visitors) where there has been death, life-saving intervention has been required, or where the event has resulted in permanent / long term harm.

5. Near misses which had the potential to result in death, or could have required life saving intervention, or could have resulted in permanent / long term harm.

6. Other environmental / organisational / financial events which could have resulted in significant harm to staff, patients, visitors, or to the organisation's reputation. Consider severe financial loss (£>1m), ongoing national adverse publicity

The above events could be identified through other various sources, Datix, complaints, litigation, mortality review, etc.

APPENDIX B - REPORTING OF INJURIES, DISEASES AND DANGEROUS OCCURENCES REGULATIONS 2013 (RIDDOR)

This Appendix has been adapted from the HSE 2013 document; "Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013: Guidance for Employees" More detailed advice on RIDDOR can be found here: http://www.hse.gov.uk/riddor/

1.0 Introduction

1.1 This appendix[1] gives guidance on how the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) applies to the health and social care sector. It is aimed at managers in both health and social care who have a duty to report under RIDDOR.

1.2 RIDDOR requires NHS Highland to report deaths, certain types of injury, some occupational diseases and dangerous occurrences that **'arise out of or in connection with work'**. Generally, this covers incidents **where the work activities, equipment or environment (including how work is carried out, organised or supervised) contributed in some way to the circumstances of the accident**.

1.3 RIDDOR reports alert enforcing authorities to events and helps them to decide whether to investigate serious incidents. Reports enable the Health and Safety Executive (the regulator that enforces Health and Safety) to identify where and how health and safety risks arise, reveal trends and help target activities.

1.4 Some incidents are not reportable under RIDDOR. But this does not mean that the general provisions of the Health and Safety at Work etc Act 1974 ('the HSW Act') do not apply. Depending on the circumstances, the HSE may decide it is appropriate to investigate such incidents, and these **may** involve clinically related incidents. This is more likely to arise where serious management failures have contributed to, or had the potential to cause, death or serious injury.

[1] *Adapted from HSE, 2013, Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013: Guidance for Employees*

2.0 What do you need to report?

The following are reportable, **if they "arise out of or in connection with work":**

- the death of any person, whether or not they are at work (see Section 1);
- accidents which result in an employee or a self-employed person dying, suffering a specified injury, being absent from work or unable to do their normal duties for more than seven days (see Section 2);
- accidents which result in a person not at work (e.g. a patient, service user, client, visitor) suffering an injury and being taken directly to a hospital for treatment, or if the accident happens at a hospital, if they suffer a specified injury (see Section 3);

- an employee or self-employed person has one of the specified occupational diseases or is exposed to carcinogens, mutagens and biological agents (see Section 2);
- specified dangerous occurrences, which may not result in a reportable injury, but have the potential to do significant harm (see Section 4).

3.0 Who should report?

3.1 The 'responsible person' has the duty to notify and report. This may be NHS Highland as the employer of an injured person, a self-employed person or someone in control of premises where work is carried out. Who the responsible person is depends on the circumstances of the reportable incident (see Table 1).

3.2 The employment status of agency workers is not always clear. In many cases, the employment agency is the legal employer, and is under the same legal obligations as any other employer to report accidents and ill health to their employees. In other cases, for instance where workers are self-employed, the duty is on the host business to report accidents, as the person in control of the premises where an accident occurs.

3.3 In practice, agencies should ensure that responsibility for reporting under RIDDOR is clearly assigned to the appropriate person based on the particular facts of the employment relationship. Agencies should ensure that reporting responsibilities are clearly understood by the host businesses and workers.

3.4 Where different organisations share responsibility for managing staff, the employer is responsible for ensuring adequate arrangements are in place for reporting incidents.

Table 1 - The Responsible Person

Reportable Incident	Injured Person	Responsible Person
Death, specified injury, over-seven-day injury or case of disease	An employee at work	NHS Highland
Death, specified injury or over-seven- day injury	A self-employed person at work in premises under someone else's control	The person in control of the premises
Specified injury, over-seven-day injury or case of disease	A self-employed person at work in premises under their control	The self-employed person or someone acting on their behalf
Death or injury which means you have to be taken to hospital for treatment (or a specified injury occurring at a hospital)	A person not at work (but affected by the work of someone else), e.g. patient, volunteer or visitor	The person in control of the premises or, in domestic premises, the employer in control of the work activity

Dangerous occurrence		The person in control of the premises where (or in connection with the work at which) the dangerous occurrence happened

Failure to report a reportable injury, dangerous occurrence, or disease, in accordance with the requirements of RIDDOR, **is a criminal offence, and may result in prosecution**. **Reporting an incident is not an admission of liability.**

4.0 When to Report

4.1 Although the Regulations specify varying timescales for reporting different types of incidents, it is advisable to report the incident as soon as possible.

4.2 In cases of a reportable death, specified injury, or dangerous occurrence, you must notify the HSE without delay. You must report within 10 days of the incident. Over-seven-day injuries must be reported within 15 days of the incident

4.3 Diseases should be reported as soon as a registered medical practitioner (RMP) notifies you in writing that your employee suffers from a reportable work-related disease.

5.0 How to report

NHS Highland currently operates two systems for notifying and reporting RIDDOR to the HSE. The intention is to adopt one system in due course.

5.1 **Northern Highland**. Local Managers (DATIX Handler's) are to make initial RIDDOR notifications through the DATIX system. Alerts are generated to Operational HS Managers and the HS Administrator (01463 704607) at John Dewar Building, Inverness, who will then make initial checks with local managers, health and safety staff etc and then formally notify the Health and Safety Executive directly.

5.2 **Adult Social Care Units**. Local Managers are to are to make initial RIDDOR notifications through DATIX, and then report the incident, within the specified timeframes, directly to the HSE by phone (especially if significant) or via the webpage which can be found here: http://www.hse.gov.uk/riddor/report.htm. It may, if required, be prudent to seek advice prior to reporting from Operational Health and Safety managers.

5.3 **Argyll &Bute CHP.** Local Managers are to are to make initial RIDDOR notifications through DATIX, and then report the incident, within the specified timeframes, directly to the HSE by phone (especially if significant) or via the webpage which can be found here: http://www.hse.gov.uk/riddor/report.htm. It may, if required, be prudent to seek advice prior to reporting from Operational Health and Safety managers.

6.0 Keeping records

6.1 The regulations require NHS Highland to retain records of any reportable injury, disease or dangerous occurrence for three years. NHS Highland must still keep a record of all over-three-day injuries. This must include:

- the date and method of reporting;
- the date, time and place of the event;
- personal details of those involved;
- the injury;
- a brief description of the nature of the event or disease.

6.2 In Northern Highland once the RIDDOR report has been notified to the HSE, a copy will be appended to the relevant DATIX report.

6.3 Managers in Adult Social Care Units and Argyll and Bute CHP are to retain the Cc email copy (generated through the HSE website) and append it to the relevant DATIX report.

7.0 Consultation

7.1 Under the Safety Representatives and Safety Committees Regulations 1977 and the Health and Safety (Consultation with Employees) Regulations 1996, NHS Highland must make relevant health and safety documents available to safety representatives.

7.2 This includes records kept under RIDDOR, except where they reveal someone's personal health information.

8.0 Reporting requirements of other regulators

8.1 Other regulators in the health and social care sector administer a number of reporting requirements. These are separate to and distinct from the legal duty to report incidents under RIDDOR.

8.2 Sometimes regulators need to share information in accordance with their statutory responsibilities, especially where it may indicate a failure to follow legal responsibilities and put people at risk.

RIDDOR Section 1: Deaths in Health and Social Care

1. You must report the death of any person, **whether or not they are at work**, if it is caused by an accident **arising out of or in connection with work**. However, under RIDDOR there is no requirement on anyone to report the death of:

- A self-employed person in premises where they are the owner or occupier; or

- An employee which occurs after one year from the date of the accident. If an employee dies after some delay as a result of an injury which is reportable, NHS Highland must inform the enforcing authority about the death in writing, provided that it occurs within a year of the date of the incident. You must do this whether or not the original injury had been reported.

Deaths which are NOT reportable

- A patient or service user commits suicide. Suicides are not considered 'accidents' and are not RIDDOR reportable.
- A service user admitted to hospital for treatment contracts Legionnaires' disease and dies while in hospital. The death has to be caused by an accident to be reportable. Poor maintenance on a hot water system would not be considered an 'accident'.

2. Although RIDDOR does not apply in these instances, the general provisions of the Health and Safety at Work etc Act 1974 could still apply. The enforcing authority may, depending on the circumstances, decide it is appropriate to investigate such incidents. This is more likely to arise where serious management failures were a contributory factor.

Reporting Legionnaires' disease cases to other organisations

- *Health Protection Scotland (HPS)*
  In Scotland the diagnostic laboratory has the duty to notify the local health board and Health Protection Scotland of any identified cases of Legionnaires' disease. This should be an urgent notification, i.e. within the same working day of

Identification, followed up in writing within ten days. You can find more information on the HPS website at www.hps.scot.nhs.uk.

Section 2: Injuries and Ill Health Involving Health and Social Care Workers e.g. Staff

This section covers accidents resulting in an employee or a self-employed person suffering a specified injury, or being absent from work or unable to do their normal duties for more than three days.

1. Specified injuries

The following are reportable specified injuries if they **"arise out of or in connection with work"**:

- fractures, other than to fingers, thumbs and toes;
- amputations;
- any injury likely to lead to permanent loss of sight or reduction in sight;
- any crush injury to the head or torso causing damage to the brain or internal organs;
- serious burns (including scalding) which: – cover more than 10% of the body; or – cause significant damage to the eyes, respiratory system or other vital organs;
- any scalping requiring hospital treatment;
- any loss of consciousness caused by a head injury or asphyxia;

- any other injury arising from working in an enclosed space which:
  - leads to hypothermia or heat-induced illness; or
  - requires resuscitation or admittance to hospital for more than 24 hours.

2. Lost-time accidents to employees

- ***Over-seven-day injuries***
  Accidents must be reported where they result in an employee or self-employed person being away from work, or unable to perform their normal work duties, for more than seven consecutive days as the result of their injury. The seven-day period does not include the day of the accident, but does include weekends and rest days.

- ***Over-three-day injuries***
  You must record accidents, but not report them where they result in a worker being incapacitated for more than three consecutive days. If you are an NHS Highland, who has to keep an accident book, the record you make in this will be enough

- ***Physical violence***.
  A physical injury inflicted on one employee by another during a dispute about a personal matter, or an employee at work injured by a relative or friend who visits them at work about a domestic matter, is not reportable.

  However, other acts of non-consensual violence to a person at work that result in death, a major injury or being incapacitated for over seven days are reportable and you must keep a record of over-three-day injuries.

3. Diseases, Infections and Ill Health

You must report any instance where a Registered Medical Practitioner (RMP) tells you in writing that one of your employees is suffering from a disease specified in RIDDOR, and the employee undertakes work linked with that condition. In NHS Highland this is usually initiated by Occupational Health Physicians.

Reportable diseases, infections and ill health include:

- carpal tunnel syndrome;
- severe cramp of the hand or forearm;
- occupational dermatitis;
- hand-arm vibration syndrome;
- occupational asthma;
- tendonitis or tenosynovitis of the hand or forearm;
- any occupational cancer;
- any disease attributed to an occupational exposure to a biological agent.

For the purposes of RIDDOR, an infection is the entry and multiplication of an infectious agent in the body, causing a damaging reaction to the tissue. The infection and damage caused may give clinical signs and symptoms of disease, or may be subclinical or 'asymptomatic'.

Colonisation (the presence and multiplication of infectious agents in or on the body, without a damaging reaction in the tissue) is not the same as infection and is not reportable as a disease.

Infections that could have been acquired as easily in the community as in work are not reportable, unless the infection was definitely acquired at work.

Self-employed people need to make their own arrangements to notify any reportable diseases and infections they suffer (for advice on how to report, see the RIDDOR pages on HSE's website at Health and Safety Executive.

Reportable Examples

- A nurse contracts active pulmonary TB after nursing a patient with the condition.
- A laboratory worker suffers from typhoid after working with specimens containing typhoid
- A paramedic becomes hepatitis B positive after contamination with blood from an infected patient
- A care assist is splashed in the face with bodily fluids from a service user and becomes hepatitis B positive.
- A surgeon suffers dermatitis associated with wearing latex gloves during surgery.
- A maintenance worker contracts Legionnaires' disease after working on the hot water system.
- In all of these cases it is clear that the disease is either attributable or contributed to by the work activity and an RMP has confirmed that this is the case.

Not reportable Examples

- A nurse becomes colonised with MRSA and works with patients infected with MRSA.
- A cleaner catches chicken pox. Patients in areas where she has worked have chicken pox.
- A care home assistant is off work with influenza for two weeks, the influenza cannot be reliably attributed to their work activity, as it is common in the community.

In all of these cases, either infection has not occurred at work or the disease cannot be reliably attributed to the work activity, as it might easily have occurred at home or in the community.

4. Sharps injuries

A sharps injury is when a needle or other sharp instrument accidentally penetrates the skin. It is sometimes called a needlestick injury.

Sharps injuries **must** be reported:

- When an employee is injured by a sharp known to be contaminated with a blood-borne virus (BBV), e.g. hepatitis B or C or HIV. This is reportable as a dangerous occurrence;
- When the employee receives a sharps injury and a BBV acquired by this route sero-converts. This is reportable as a disease – see 'Diseases, infections and ill health';
- If the injury itself is so severe that it must be reported.

If the sharp is not contaminated with a BBV, or the source of the sharps injury cannot be traced, it is not reportable, unless the injury itself causes an over-seven-day injury. If the employee develops a disease attributable to the injury, then it **must** be reported.

Reportable Example

- A cleaner suffers a needlestick injury from a needle and syringe known to contain hepatitis B positive blood (reportable as a dangerous occurrence).

Not reportable Examples

- A community nurse suffers a needlestick injury; does not sero-convert and the source of the sharp cannot be traced.
- A laboratory worker is injured by a blood specimen container. The patient is not known to have any infection.
- An employee is cut with a scalpel used on a patient not known to be contagious, but undergoing blood checks for hepatitis A.

Due to the sensitive nature of reporting diseases and infections caused by blood-borne viruses, the enforcing authority does not require you to name the injured person on the RIDDOR report. However, if the enforcing authority decides to investigate, you may be asked to provide this information. If it is a repeat incident to the same person, you need to inform the enforcing authority.

5. Stress

Stress is **not** reportable as an occupational injury, even when accompanied by a medical certificate stating it is work-related, because it does not result from a single definable accident.

Section 3: Injuries and Ill Health Involving People Not at Work For Example Patients, Clients, Contractors, Visitors etc

This section covers accidents which result in a person not at work suffering an injury and being taken to a hospital, or if the accident happens at a hospital, suffering a specified injury which would have required hospital treatment.

Any injury to someone not at work must be reported if it results from an accident **"arising out of or in connection with work"** being undertaken by others and it:

- results in them being taken from the premises where the accident occurred directly to a hospital for treatment*, by whatever means (for example by taxi, private car or ambulance); or
- happens at a hospital and involves a specified injury.

*Examinations and diagnostic tests do not constitute 'treatment'.

In the past, there has been some misunderstanding as to the range of accidents that should be reported under RIDDOR when they involve members of the public who are patients, residents, service users or visitors. The following examples will help you decide about reportability.

1. Injuries to People Not at Work

Reportable Examples

- A patient is scalded by hot bath water and taken to hospital for treatment. The patient was vulnerable and adequate precautions were not taken.
- A service user receives a fractured arm when their arm becomes trapped in a bed rail.

- A visitor to the hospital is struck on the head by a car park barrier and receives a specified injury that requires hospital attention.
- A service user requires hospital treatment after sliding through a sling after being hoisted from a chair. The wrong-sized sling was used.

Not reportable Examples

- A patient or visitor is injured by an act of physical violence from another patient.
- A patient receives a healthcare-associated infection while receiving treatment in hospital. Hospital associated infections acquired by patients are not reportable under RIDDOR.
- A patient admitted to hospital for treatment contracts Legionnaires' disease in hospital.

2. Patient/ Service User Fall Incidents

A fall is reportable under RIDDOR when it has **arisen out of or in connection with a work activity**. This includes where equipment or the work environment (including how or where work is carried out, organised or supervised) are involved.

Reportable Examples

- A confused patient falls from a hospital window on an upper floor and is badly injured.
- A service user falls in the lounge area, there is previous history of fall incidents, but reasonably practicable measures to reduce the risks have not been put in place.
- A service user falls out of bed, is injured and taken to hospital. The assessment identified the need for bedrails but they, or other preventative measures, had not been provided.
- A service user trips over a loose or damaged carpet in the hallway.

Not reportable Examples

- A service user falls and breaks a leg. They were identified as not requiring special supervision or falls prevention equipment. There are no slips or trips obstructions or defects in the premises or environment, nor any other contributory factors.
- A service user falls out of bed and is taken to hospital. There was a detailed assessment in the care plan identifying that fall protection was not required.
- A service user is found on the floor, no-one has seen it happen, and/or there are no obvious work- related contributing factors. There was a detailed assessment in the care plan, which identified that fall protection was not required.

In some circumstances, it may not be clear whether the accident that caused the injury arose out of or was connected to the work activity.

Example 1

A service user (who is capable of understanding and following advice) falls off the toilet, having previously been advised not to get up, is injured and taken to hospital. They have been left alone for dignity reasons. Their care plan identified that the individual should have assistance or supervision.

Reportable

- The member of staff left the service user out of earshot and without a call bell they could use, or had not responded promptly when they did call, as adequate supervision had not been provided.

Not reportable

- The member of staff returned to help them as soon as they called to say they have finished. Or if the service user had got up without calling for help, it would not be reportable.

Example 2

An incontinent service user slips on their own urine when returning back from the toilet and receives a major injury.

Reportable if:

- the assessment had identified the resident needed help for toileting and it was not provided;
- the fall took place in an area of the home where it was foreseeable the resident may slip due to a spillage and the home had failed to assess risks from floor surfaces or act on their assessment.

Example 3

A patient falls from a stretcher while being manoeuvred into an ambulance and suffers a hip fracture.

Reportable if:

- the paramedics had chosen the wrong piece of equipment to move the patient, or had not received the appropriate training about safe use of the equipment, or were not following a safe system of work;
- the paramedics were aware the patient had a history of aggression and failed to take this into account when moving them. The patient subsequently becomes aggressive and falls from the stretcher

Not reportable if

- the patient became unexpectedly aggressive, struggled and fell.

You may need to consult the patient's/service user's care plan to decide what care was assessed as being appropriate for them. If you still are unclear, ask for advice.

3. Self-harm

Acts of deliberate self-harm are not considered 'accidents' and are not RIDDOR reportable.

However, this does not mean that the general provisions of the HSW Act do not apply. The enforcing authority may, depending on the circumstances, decide that it is appropriate to investigate such incidents. This is more likely to arise where serious management failures were a contributory factor.

4. Clinical decisions

If a person is injured as a result of an accident arising directly from the conduct of any operation, any examination or other medical treatment being carried out by or under the supervision of an RMP or registered dentist, the injury is not reportable.

The supervision does not need to be direct for the exemption to apply – it is sufficient that the procedure being carried out was laid down by an RMP.

Reportable

- A patient suffering a serious injury as a result of a power failure during an operation (not caused by the conduct of the operation).

Not reportable

- During a surgical operation, a surgeon removes the wrong organ. The patient subsequently dies.
- A patient suffers a seizure following a medical procedure. The nursing assistant was following a procedure laid down by an RMP.
- A paramedic administers a drug to a patient who subsequently dies because of an allergic reaction. This would not be reportable, whether or not the correct procedure was being followed.
- A patient known to be allergic to penicillin is nevertheless given a penicillin-based drug under the supervision of an RMP and subsequently dies.

If there is a concern about the professional misconduct of an individual, you should ensure that the appropriate professional body is notified:

- General Medical Council for doctors;
- General Dental Council for dentists;
- Nursing and Midwifery Council for nurses;
- Health Professions Council for paramedics and allied health professionals.

For further advice you can also contact your local Public Advice and Liaison Service or the Independent Complaints Advisory Service.

Section 4: Dangerous Occurrences in Health and Social care

Dangerous occurrences are certain specified near-miss events, which may not result in a reportable injury, but have the potential to do significant harm.

Reportable dangerous occurrences include the following:

- the collapse, overturning or failure of load-bearing parts of lifts and lifting equipment;
- the accidental release of a biological agent likely to cause severe human illness (a hazard group 3 or 4 pathogen);
- the accidental release or escape of any substance which may cause a major injury or damage to health;
- an electrical short circuit or overload causing fire or explosion;
- the explosion, collapse or bursting of any closed vessel or associated pipework forming a pressure system;

- an explosion or fire causing suspension of normal work for over 24 hours.

RIDDOR includes a full list of dangerous occurrences. For more information on the reportability of sharps injuries see Section 2.

Is the incident a reportable dangerous occurrence?

Reportable

- A patient hoist collapses or overturns.
- A laboratory worker spills a sufficient quantity of formaldehyde from a container to cause damage to the health of a worker or others present.
- A container of a TB culture is broken and releases its contents.
- A cleaner suffers a needlestick injury from a needle and syringe known to contain hepatitis B positive blood.

Not reportable

- An elderly woman with dementia wanders out of a care home into the car park/main road.
- There is a collision between two vehicles in a hospital car park and no-one is injured.
- A lifting sling fails during a lift. You don't need to report failures of lifting accessories.
- A community nurse suffers a needlestick injury, does not sero-convert and the source of the sharp cannot be traced.

APPENDIX C: TYPES OF ADVERSE EVENTS TO BE REPORTED

RLDatix™

TYPES OF INCIDENTS TO BE REPORTED ON DIF1

January 2020

Category (Pick List 1)	Sub Category / Cause (Pick List 2)	
Absconder / Wandering / Missing Patient	• Missing patient • Failure to return from authorised leave • Vulnerable/confused patients leaving the ward area	
Access/Admission	• Delay or failure in access to hospital or care • Unexpected re-admission or re-attendance • Unplanned admission or transfer to specialist care unit	
Accident	• Cause unknown • Choking • Contact with electricity and electrical discharges • Contact with hot or very cold surface or object • Contact with moving machinery/equipment • Explosion/pressure release • Exposure to fire	• Exposure to or contact with a biological agent • Exposure to or contact with a harmful substance • Struck by a moving, including flying or falling object • Struck by a moving vehicle • Struck by something (eg furniture, fittings etc) • Trapped by something collapsing
Bed management	• Lack of or delayed availability in specialist unit • Lack of or delayed availability of beds (general) • Lack of or delayed availability of beds (high dependency / intensive care/SCBU) • Lack of or delayed availability of operating theatre	
Blood transfusion	• Adverse reaction • Blood spillage • Failure to follow procedures • Sampling error • Wastage	
Business continuity	• Disruption to supply chain • Loss / denial of access to building / department • Loss of IT • Loss of staff • Loss of telecoms • Loss of transport • Loss of utilities	
Clinical assessment	• Delay / difficulty in obtaining clinical assistance • Delay or failure to monitor • Diagnosis - delay or failure to diagnose • Incorrect diagnosis • Lack of clinical or risk assessment	
Clinical event	• Unexplained / unexpected / avoidable complication • Unexplained / unexpected / avoidable death • Unexplained / unexpected / avoidable morbidity	
Communication, confidentiality	• Breach of patient confidentiality • Communication failure - outside of immediate team • Communication failure - with patient/parent/carer • Communication failure - within team • IT / telecommunications failure / overload	
Consent	• Failure to receive informed consent • Failure to follow withdrawal of consent	
Discrimination or hate incident (on grounds of age, gender, disability, sexual orientation, religion, race)	• Age • Disability (physical, mental or learning) • Marriage or civil partnership • Race • Religion or belief • Sexual orientation (lesbian, gay, bisexual or straight) • Sex (male or female) • Sex (transgender)	
Documentation / clinical information	• Appointment recording error • Delay in obtaining healthcare record / card • Failure to follow up missed appointment • Hardware problems • Healthcare record / card – mislabelled • Misfiled documentation • Missing / inadequate/illegible healthcare record/card	• Missing / inadequate / illegible referral letter • Multiple numbers for individual patient • Network problems • No access to documentation • One number for multiple patients • Software problems • Theatre list details incorrect
Estates, Buildings & Works	• Cables or pipes cut or damaged • Contamination • Contractors non compliance • Dust • Faults • Noise • Smells/fumes • Spills	

	• Vibration	
Falls, Slips & Trips	• Controlled fall, assisted to floor or chair • Fall from a height less than 2 meters • Fall from a height more than 2 meters • Suspected / unwitnessed fall • Slip, trip fall on level ground • Tripped	
Fire	• Failure with alarm system • Fire (actual) • Unauthorised smoking • Unwanted fire alarm signal (false alarm)	
Infection Control	• Catheter Associated Urinary Tract (CAUTI) • Failure of sterilisation or contamination of equipment • Failure to notify infection status • Infection – Surgical site infection • Infection – Clostridium difficile • Infection – Staphylococcus aureus bacteraemia (SAB) • Outbreaks • Unsafe or inappropriate clinical environment (including clinical waste)	
Investigations (Scans / X-rays / spécimens)	• Delay / failure to investigate • Inadequate or incomplete request card • Inadequate or incomplete specimen • Incorrect investigation • Magnetic Resonance Adverse Event – Clinical • Magnetic Resonance Adverse Event - Safety • Mislabelled or unlabelled • Missing • Patient incorrectly identified	
Medical device / all equipment (except radiation equipment)	• Failure of medical device / equipment during inspection • Failure of medical device / equipment during operation • Failure to perform scheduled maintenance check • Failure to perform statutory maintenance check • Lack of training in medical device/equipment use • Lack or unavailability of medical device / equipment • User error • Wrong medical device / equipment used	
Medication (including vaccines)	• Prescribing • Prescribing and administration • Preparation • Administration • Monitoring • Dispensing • Patient reaction	• Advice • Broken / dropped / spoilt drug • Cold Chain Breach (temp outwith 2-8 degrees C) • Controlled drug register discrepancy • Defective medication • Inappropriate / insecure storage • Missing/stolen drugs • Supply
Moving & handling	• Environment/equipment restricting Moving and Handling • Non patient lifting/putting down/pushing/pulling/carrying/supporting/lowering/reaching • Patient lifting/handling/supporting • Patient transfer assisted with equipment • Patient transfer assisted without equipment	
Occupational diseases (potential)	• Conditions due to physical agents and physical demands of work • Conditions due to substances • Infections due to biological agents	
Radiation	• Equipment fault • Failure to follow procedures/lack of procedures • Foetal dose • Incorrect/incomplete referral details • Lack of training • Loss/unavailability of films/images • Patient ID	
Road Traffic Accident (RTA)	• Ambulance or patient in RTA • Employee in RTA whilst on NHS business • Loss or damage to vehicle	
Security	• Breach of IT security • Breach of security • Hoax calls • Illicit drug dealing/misuse • Loss, harm, theft or damage to employee-owned property/assets & other whilst at work • Loss, harm, theft or damage to NHS Highland property/assets • Loss, harm, theft or damage to patients property • Trespassers	
Self-harming behaviour	• Self-harm • Substance misuse • Suspected suicide (actual) • Suspected suicide (attempted)	
Sharps	• Contact with a needle or other sharp • Cut with a sharp material or object (not medical sharp)	
Staff Availability	• Breakdown of planned staff coverage arrangements • Failure of pre-employment processes • Failure to return from authorised leave	

	• Inadequate arrangements for expected staff shortages • Lack of suitably trained/skilled staff • Unexpected staff shortage	
Test Results and Reports	• Failure or delay to interpret or act on • Failure or delay to receive • Failure or delay to undertake • Incorrect • Patient incorrectly identified	
Tissue viability (inc pressure ulcers	• Device related pressure ulcer • Pressure Ulcer Grade 1 • Pressure Ulcer Grade 2 • Pressure Ulcer Grade 3 • Pressure Ulcer Grade 4 • Ungradable • Deep Tissue Injury • Other Tissue Damage (eg moisture lesions, excoriation)	
Transfer / Discharge	• Discharge – delay or failure • Discharge - inappropriate • Discharge - planning failure • Discharge - self or against medical advice • Extended stay or episode of care	• Failure in referral process • Transfer - delay or failure • Transport – inappropriate • Transport - delay or failure
Treatment, procedure	• Delay or failure in recognising complication of treatment • Incorrect patient identified for treatment/procedure • Incorrect site of surgery • Infusion injury (extravasation) • Missing needle / swab / instrument • Retained needle / swab / instrument	• Site of surgery not marked • Treatment not clinically indicated • Treatment / procedure – cancellation of procedure • Treatment / procedure - delay or failure • Treatment / procedure - inappropriate or incorrect • Unplanned return to theatre
Violent, Aggressive, Disruptive behaviour	• Accusation/intimidation • Aggressive behaviour (non-physical) • Damage to property/personal belongings • Physical • Verbal	
Workforce bullying and harassment	• Telephone abuse • Verbal abuse, face to face • Written abuse	
Other	• Other	

NB: any near miss incidents involving a potential adverse event described above MUST also be reported.

APPENDIX D

ADVERSE EVENT GRADING TOOLS

1. Assessment of Severity

Assessment of severity should include consideration of the potential consequence of the adverse event as well as the actual consequence.

Descriptor	Negligible	Minor	Moderate	Major	Extreme
Patient Experience	Reduced quality of patient experience / clinical outcome not directly related to delivery of clinical care.	Unsatisfactory patient experience / clinical outcome directly related to care provision – readily resolvable.	Unsatisfactory patient experience / clinical outcome, short term effects – expect recovery <1wk.	Unsatisfactory patient experience / clinical outcome: long term effects – expect recovery - >1wk.	Unsatisfactory patient experience / clinical outcome: continued ongoing long term effects.
Injury (physical and psychological) to patient / visitor / staff.	Adverse event leading to minor injury not requiring first aid	Minor injury or illness, first aid treatment required	Agency reportable, e.g. Police (violent and aggressive acts) Significant injury requiring medical treatment and/or counselling.	Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling.	Incident leading to death or major permanent incapacity.
Complaints / Claims	Locally resolved verbal complaint	Justified written complaint peripheral to clinical care.	Below excess claim. Justified complaint involving lack of appropriate care.	Claim above excess level. Multiple justified complaints.	Multiple claims or single major claim. Complex justified complaint.
Staffing and Competence	Short term low staffing level temporarily reduces service quality (< than 1 day). Short term low staffing level (> 1 day), where there is no disruption to patient care.	Ongoing low staffing level reduces service quality. **Minor error** due to ineffective training/implementation of training.	Late delivery of key objective / service due to lack of staff. **Moderate error** due to ineffective training/implementation of training. Ongoing problems with staffing levels.	Uncertain delivery of key objective / service due to lack of staff. **Major error** due to ineffective training/implementation of training.	Non-delivery of key objective / service due to lack of staff. Loss of key staff. **Critical error** due to ineffective training/implementation of training.
Financial (including damage/ loss/ fraud)	Negligible organisational/personal financial loss (< £1k) (**NB**. Please adjust for context)	Minor organisational/personal financial loss (£1-10k).	Significant organisational/personal financial loss (£10-100k).	Major organisational/personal financial loss (£100k - £1m).	Severe organisational/personal financial loss (>£1m).
Adverse Publicity / Reputation	Rumours, no media coverage Little effect on staff morale	Local media coverage – short term. Some public embarrassment. Minor effect on staff morale / public attitudes.	Local media – long-term adverse publicity. Significant effect on staff morale and public perception of the organisation	National media / adverse publicity, less than 3 days. Public confidence in the organisation undermined Use of services affected	National / International media / adverse publicity, more than 3 days. MSP / MP concern (Questions in Parliament). Court Enforcement Public Enquiry / FAI

2. Assessment of Likelihood

Descriptor	Rare	Unlikely	Possible	Likely	Almost Certain
Probability	Can't believe this will ever happen again – will only happen in exceptional circumstances	Not expected to happen again, but definite potential exists	Has happened before on occasions – reasonable chance of re-occurring	Strong possibility that this could happen again	This is expected to frequently happen again – more likely to re-occur than not

3. Risk Matrix

Each adverse event should be assessed and scored for likelihood and severity and the results plotted on the risk matrix:

LIKELIHOOD	CONSEQUENCES / IMPACT				
	Negligible	Minor	Moderate	Major	Extreme
Almost Certain	MEDIUM	HIGH	HIGH	VERY HIGH	VERY HIGH
Likely	MEDIUM	MEDIUM	HIGH	HIGH	VERY HIGH
Possible	LOW	MEDIUM	MEDIUM	HIGH	HIGH
Unlikely	LOW	MEDIUM	MEDIUM	MEDIUM	HIGH
Rare	LOW	LOW	LOW	MEDIUM	MEDIUM

4. Categorisation

Category 1 – Events that may have contributed to or resulted in permanent harm.	Impact / Consequence - Major or Extreme
Category 2 – Events that may have contributed to or resulted in temporary harm.	Impact / Consequence - Moderate
Category 3 – events that had the potential to cause harm.	Impact / Consequence - Minor Negligible

Appendix G: Extracted from Healthcare Improvement Scotland: Learning from adverse events through reporting and review 4th Edition (December 2019)

Reporting to external agencies

Specific events must be reported to external organisations. This includes:

- From 01 January 2020, all significant adverse event reviews commissioned by the NHS boards for a category 1 adverse event should be reported to **Healthcare Improvement Scotland (HIS)** in alignment with the new national notification system. Note: Will be submitted by Clinical Governance Support Team

- deaths and injuries due to a work related accident to the **Health and Safety Executive** as set out in the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) (See appendix A)

- events involving health, adult social care, estates and facilities equipment to the **Incident Reporting and Investigation Centre (IRIC)** within Health Facilities Scotland as set out in CEL 43 (2009)

- events relating to blood to the **Medicines and Healthcare Products Regulatory Agency (MHRA)** as required by the UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive

- adverse drug reactions, defective medicines and counterfeit medicines via the Yellow Card Scheme to the **MHRA**

- suicides of individuals in contact with mental health services to **Healthcare Improvement Scotland**

- sudden deaths associated with medical or dental care to the **Procurator Fiscal**

- relevant information to UK-wide national audits and enquiries managed by the **Healthcare Quality Improvement Partnership (HQIP)**

- information governance events to the eHealth Division within **Scottish Government** and the **Information Commissioners Office**

- Ionising Radiation adverse events to the Healthcare Improvement Scotland hcis.irmer@nhs.net

- All deaths of patients subject to mental health detention or a community based order under the 2003 Act of the Criminal Procedure (Scotland) Act; all homicides committed by people with recent contact with mental health services; and serious crimes (serious assault, serious sexual assault) by an individual who is receiving care from mental health or learning disability services are notified to the **Mental Welfare Commission for Scotland**.

The organisation should ensure there are appropriate arrangements in place to enable both local reporting and reporting to external agencies so individuals can easily meet the reporting requirements. For example, onward reporting to external agencies could be managed centrally by specialist teams.